

PCTWORLD INTELLECTUAL PROPERTY ORGANIZATION
International Bureau

INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

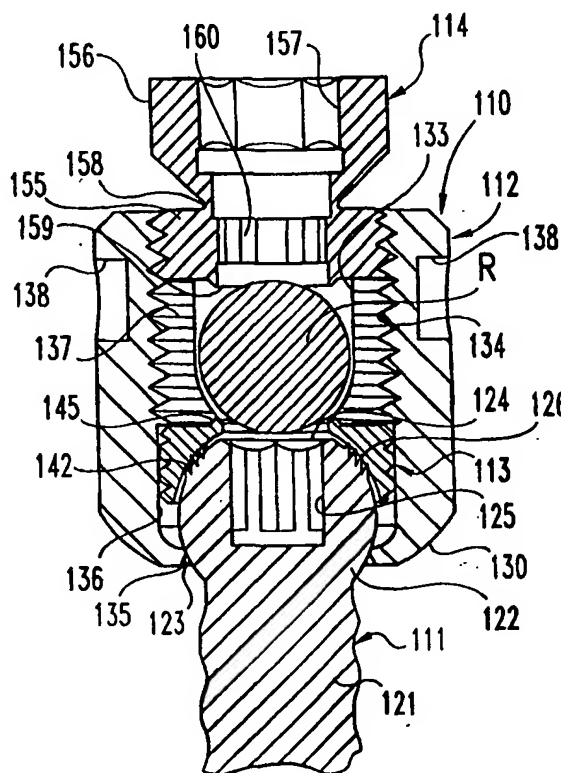
(51) International Patent Classification ⁶ : A61B 17/70		A1	(11) International Publication Number: WO 98/34554
			(43) International Publication Date: 13 August 1998 (13.08.98)
(21) International Application Number: PCT/US98/02646			(81) Designated States: AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GE, GH, GM, GW, HU, ID, IL, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, UA, UG, US, UZ, VN, YU, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG).
(22) International Filing Date: 10 February 1998 (10.02.98)			
(30) Priority Data: 08/798,872 11 February 1997 (11.02.97) US			
(71) Applicant (for all designated States except US): SDGI HOLDINGS, INC. [US/US]; Suite 508, 300 Delaware Avenue, Wilmington, DE 19801 (US).			
(72) Inventors; and (75) Inventors/Applicants (for US only): SHERMAN, Michael, C. [US/US]; 5854 Haymarket Road, Memphis, TN 38119 (US). DREWRY, Troy [US/US]; 3841 Highland Park Place, Memphis, TN 38111 (US).			
(74) Agents: REEVES, Charles, R. et al.; Woodard, Emhardt, Naughton, Moriarty & McNett, Bank One Center/Tower, Suite 3700, 111 Monument Circle, Indianapolis, IN 46204 (US).			

Published*With international search report.*

(54) Title: MULTI-AXIAL BONE SCREW ASSEMBLY

(57) Abstract

A multi-axial bone engaging fastener assembly (10) includes a bone screw (11) having a partially spherical head (22) truncated at an upper surface (24). The assembly (10) includes a receiver member (12) including a central bore (34) that defines a tapered recess (35) to receive the head of the bone screw. The bore (34) also defines a channel (33) communicating with the recess and configured to receive a spinal rod (R) therein. A portion (37) of the bore (34) is threaded to receive a set screw (14) above the rod. The assembly (10) also includes a crown member (13) disposed between the rod (R) and the bone screw head (22). As the set screw (14) is tightened to compress the rod (R) against the crown member (13), which presses the head (22) of the bone screw into the tapered recess (35). The bone screw head (22) can include a flared edge (26) or circumferential ridges (126) that penetrate at least the crown member (13) as the assembly is tightened. In a further aspect, the crown member (113) can be threaded (141) to be inserted by threading through the threaded portion (37) of the receiver member (12).



FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AL	Albania	ES	Spain	LS	Lesotho	SI	Slovenia
AM	Armenia	FI	Finland	LT	Lithuania	SK	Slovakia
AT	Austria	FR	France	LU	Luxembourg	SN	Senegal
AU	Australia	GA	Gabon	LV	Latvia	SZ	Swaziland
AZ	Azerbaijan	GB	United Kingdom	MC	Monaco	TD	Chad
BA	Bosnia and Herzegovina	GE	Georgia	MD	Republic of Moldova	TG	Togo
BB	Barbados	GH	Ghana	MG	Madagascar	TJ	Tajikistan
BE	Belgium	GN	Guinea	MK	The former Yugoslav Republic of Macedonia	TM	Turkmenistan
BF	Burkina Faso	GR	Greece	ML	Mali	TR	Turkey
BG	Bulgaria	HU	Hungary	MN	Mongolia	TT	Trinidad and Tobago
BJ	Benin	IE	Ireland	MR	Mauritania	UA	Ukraine
BR	Brazil	IL	Israel	MW	Malawi	UG	Uganda
BY	Belarus	IS	Iceland	MX	Mexico	US	United States of America
CA	Canada	IT	Italy	NE	Niger	UZ	Uzbekistan
CF	Central African Republic	JP	Japan	NL	Netherlands	VN	Viet Nam
CG	Congo	KE	Kenya	NO	Norway	YU	Yugoslavia
CH	Switzerland	KG	Kyrgyzstan	NZ	New Zealand	ZW	Zimbabwe
CI	Côte d'Ivoire	KP	Democratic People's Republic of Korea	PL	Poland		
CM	Cameroon	KR	Republic of Korea	PT	Portugal		
CN	China	KZ	Kazakhstan	RO	Romania		
CU	Cuba	LC	Saint Lucia	RU	Russian Federation		
CZ	Czech Republic	LI	Liechtenstein	SD	Sudan		
DE	Germany	LK	Sri Lanka	SE	Sweden		
DK	Denmark	LR	Liberia	SG	Singapore		
EE	Estonia						

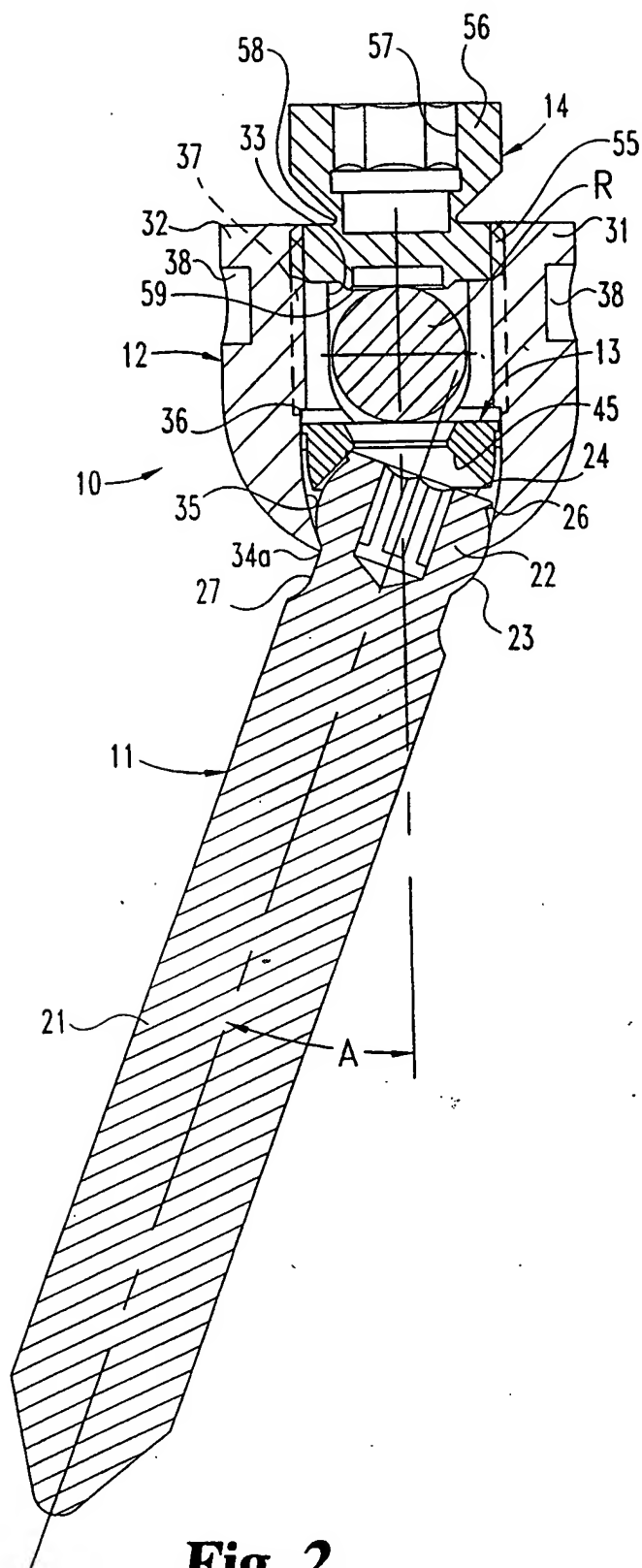


Fig. 2

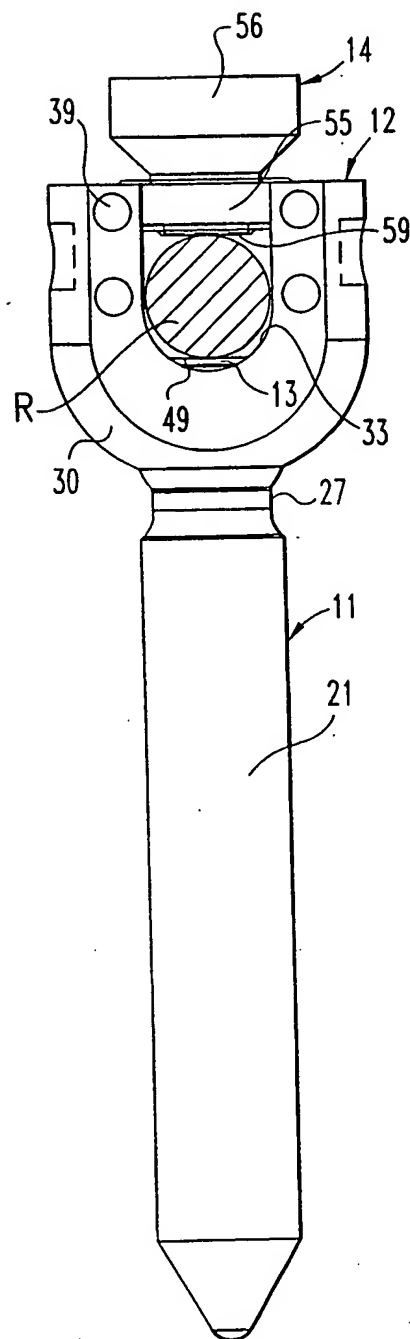


Fig. 1

SUBSTITUTE SHEET (RULE 26)

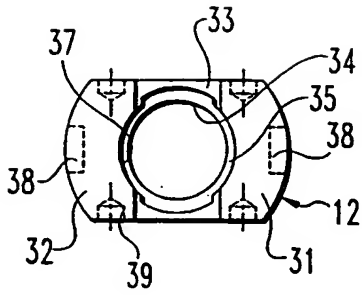


Fig. 4

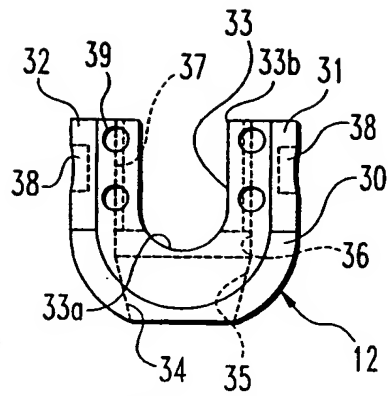


Fig. 5

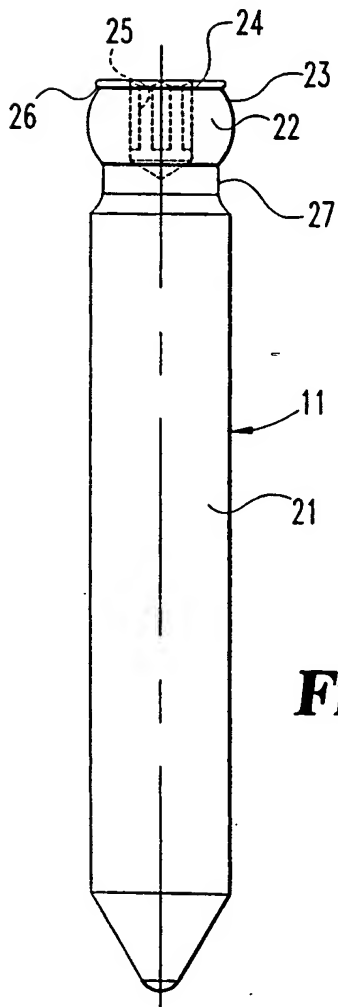


Fig. 3

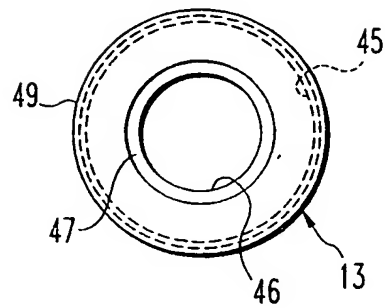


Fig. 6

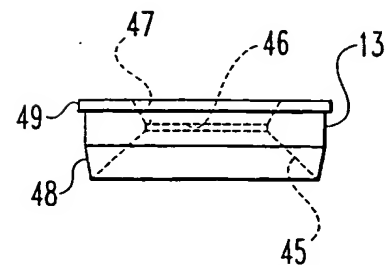


Fig. 7

3/3

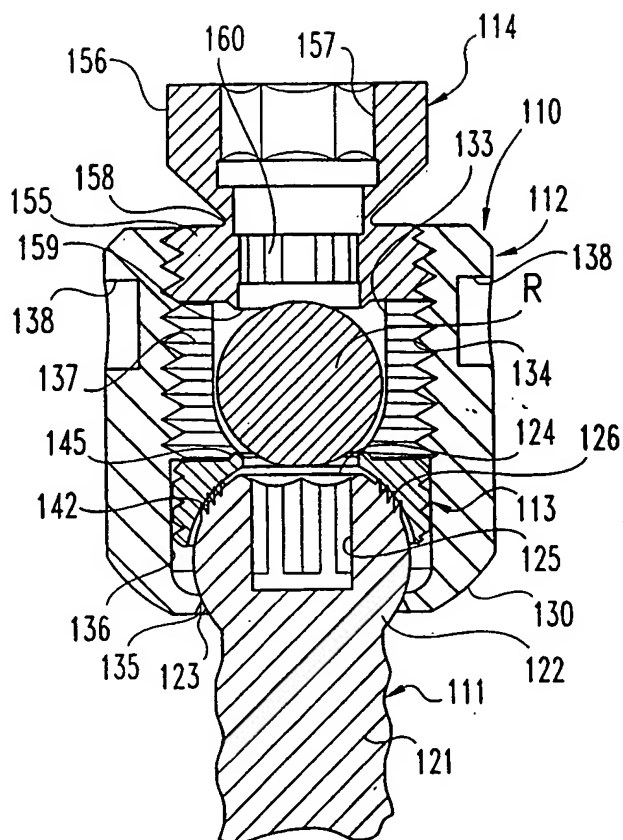


Fig. 8

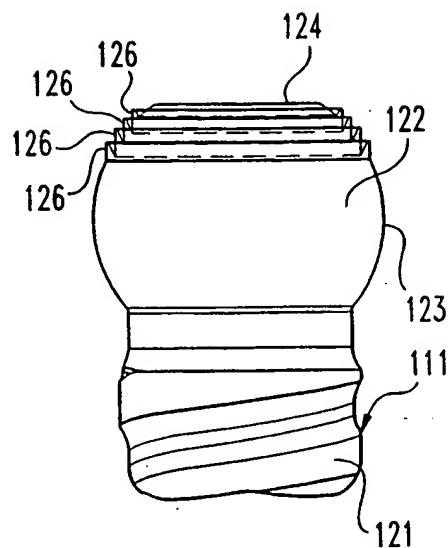


Fig. 9

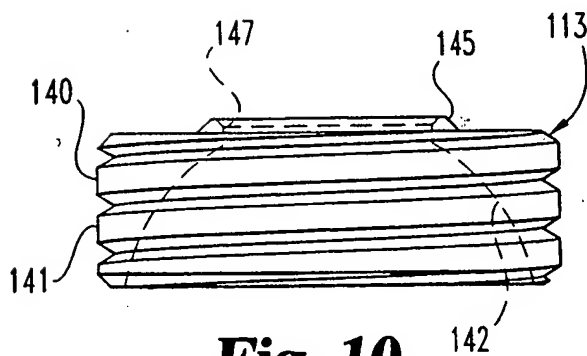


Fig. 10

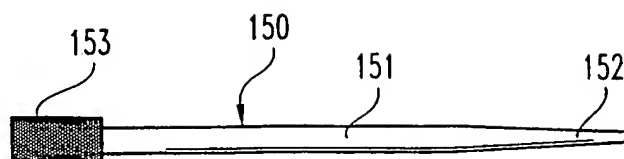


Fig. 11

SUBSTITUTE SHEET (RULE 20)

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US98/02646

A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) :A61B 17/70

US CL :606/61

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 606/60, 61, 72, 73; 623/17

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X --- Y	US 5,443,467 A (BIEDERMANN et al.) 22 August 1995, entire reference.	1-3, 6-9, 12, 17, 18 ----- 5
Y	US 5,584,833 A (FOURNET-FAYARD et al.) 17 December 1996, Fig. 1.	5

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:	*T* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
A document defining the general state of the art which is not considered to be of particular relevance	*X* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
B earlier document published on or after the international filing date	*Y* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
L document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	*A* document member of the same patent family
O document referring to an oral disclosure, use, exhibition or other means	
P document published prior to the international filing date but later than the priority date claimed	

Date of the actual completion of the international search

25 MARCH 1998

Date of mailing of the international search report

17 APR 1998

Name and mailing address of the ISA/US
Commissioner of Patents and Trademarks
Box PCT
Washington, D.C. 20231

Facsimile No. (703) 305-3230

Authorized officer

GUY V. TUCKER

Telephone No. (703) 308-3271

Form PCT/ISA/210 (second sheet)(July 1992)*

-1-

MULTI-AXIAL BONE SCREW ASSEMBLY

REFERENCE TO RELATED APPLICATIONS

This application is a continuation-in-part of U.S.
patent application no. 08/719,161 entitled MULTI-AXIAL BONE
5 SCREW, filed September 24, 1996 by the same inventors.

BACKGROUND OF THE INVENTION

The present invention concerns a bone screw assembly,
particularly useful for engagement in the vertebrae of the
spine. In particular, the invention contemplates a bone
10 screw assembly that is capable of achieving multiple angular
orientations with respect to an elongated rod extending
along the spine.

Several techniques and systems have been developed for
correcting and stabilizing the spine and for facilitating
15 fusion at various levels of the spine. In one type of
system, a bendable rod is disposed longitudinally along the
length of the spine or vertebral column. The rod is
preferably bent to correspond to the normal curvature of the
spine in the particular region being instrumented. For
20 example, the rod can be bent to form a normal kyphotic
curvature for the thoracic region of the spine, or a
lordotic curvature for the lumbar region. In accordance
with such a system, the rod is engaged to various vertebrae
along the length of the spinal column by way of a number of
25 fixation elements. A variety of fixation elements can be
provided which are configured to engage specific portions of
the vertebra. For instance, one such fixation element is a
hook that is configured to engage the laminae of the

-2-

vertebra. Another very prevalent fixation element is a spinal screw which can be threaded into various aspects of the vertebral bone.

5 In one typical procedure utilizing a bendable rod, the rod is situated on opposite sides of the spine or spinous processes. A plurality of bone screws are threaded into a portion of several vertebral bodies, very frequently into the pedicles of these vertebrae. The rods are affixed to these plurality of bone screws to apply corrective and
10 stabilizing forces to the spine.

One example of a rod-type spinal fixation system is the TSRH® Spinal System sold by Danek Medical, Inc. The TSRH® System includes elongated rods and a variety of hooks, screws and bolts all configured to create a segmental
15 construct throughout the spine. In one aspect of the TSRH® System, the spinal rod is connected to the various vertebral fixation elements by way of an eyebolt. In this configuration, the fixation elements are engaged to the spinal rod laterally adjacent to the rod. In another aspect
20 of the TSRH® System, a variable angle screw is engaged to the spinal rod by way of an eyebolt. The variable angle screw allows pivoting of the bone screw in a single plane that is parallel to the plane of the spinal rod. Details of this variable angle screw can be found in U.S. Patent No.
25 5,261,909 to Sutterlin et al., owned by the Assignee of the present invention. One goal achieved by the TSRH® System is that the surgeon can apply vertebral fixation elements, such as a spinal hook or a bone screw, to the spine in appropriate anatomic positions. The TSRH® System also
30 allows the surgeon to easily engage a bent spinal rod to each of the fixation elements for final tightening.

Another rod-type fixation system is the Cotrel-Dubosset/CD Spinal System sold by Sofamor Danek Group, Inc. Like the TSRH® System, the CD® System
35 provides a variety of fixation elements for engagement

-3-

between an elongated rod and the spine. In one aspect of the CD® System, the fixation elements themselves include a body that defines a slot within which the spinal rod is received. The slot includes a threaded bore into which a threaded plug is engaged to clamp the rod within the body of the fixation element. The CD® System includes hooks and bone screws with this "open-back" configuration. Details of this technology can be found in U.S. Patent No. 5,005,562 to Dr. Cotrel. One benefit of this feature of the CD® System is that the fixation element is positioned directly beneath the elongated rod. This helps reduce the overall bulkiness of the implant construct and minimizes the trauma to surrounding tissue.

On the other hand, these fixation elements of the CD® System are capable only of pivoting about the spinal rod to achieve variable angular positions relative to the rod. While this limited range of relative angular positioning is acceptable for many spinal pathologies, many other cases require more creative orientation of a bone screw, for instance, relative to a spinal rod. Certain aspects of this problem are addressed by the variable angle screw of the TSRH® System, as discussed in the '909 Patent. However, there is a need for a bone screw that is capable of angular orientation in multiple planes relative to the spinal rod. Preferably, the bone screw is capable of various three-dimensional orientations with respect to the spinal rod. Screws of this type have been referred to as poly-axial or multi-axial bone screws.

Others have approached the solution to this problem with various poly-axial screw designs. For example, in U.S. Patent No. 5,466,237 to Byrd et al., a bone screw is described which includes a spherical projection on the top of the bone screw. An externally threaded receiver member supports the bone screw and a spinal rod on top of the spherical projection. An outer nut is tightened onto the

-4-

receiver member to press the spinal rod against the spherical projection to accommodate various angular orientations of the bone screw relative to the rod. While this particular approach utilizes a minimum of components, the security of the fixation of the bone screw to the rod is lacking. In other words, the engagement or fixation between the small spherical projection on the bone screw and the spinal rod is readily disrupted when the instrumentation is subjected to the high loads of the spine, particularly in the lumbar region.

In another approach shown in U.S. Patent No. 4,946,458 to Harms et al., a spherical headed bone screw is supported within separate halves of a receiver member. The bottom of the halves are held together by a retaining ring. The top of the receiver halves are compressed about the bone screw by nuts threaded onto a threaded spinal rod. In another approach taken by Harms et al., in U.S. Patent No., 5,207,678, a receiver member is flexibly connected about a partially spherical head of a bone screw. Conical nuts on opposite sides of the receiver member are threaded onto a threaded rod passing through the receiver. As the conical nuts are threaded toward each other, the receiver member flexibly compresses around the head of the bone screw to clamp the bone screw in its variable angular position. One detriment of the systems in the two Harms et al. patents is that the spinal rod must be threaded in order to accept the compression nuts. It is known that threaded rods can tend to weaken the rods in the face of severe spinal loads. Moreover, the design of the bone screws in the '458 and '678 Patents require a multiplicity of parts and are fairly complicated to achieve complete fixation of the bone screw.

There is therefore a need remaining in the industry for a multi-axial or poly-axial bone screw that can be readily and securely engaged to an elongated spinal rod. Preferably, the spinal rod can be of any configuration -

-5-

i.e., smooth, roughened, knurled or even threaded. This need also encompasses the need for minimizing the profile and bulk of any of the components used to engage the bone screw to the spinal rod in a variety of angular
5 orientations.

-6-

SUMMARY OF THE INVENTION

In one embodiment of the invention, a spinal fixation assembly is provided that includes a bone engaging fastener, or bone screw, and an elongated member, such as a spinal rod. The fixation assembly includes a multi-axial assembly that permits fixation of the bone screw to the spinal rod at any of a plurality of angles in three-dimensional space relative to the rod. In one aspect of the invention, the bone screw includes a head that is partially spherical. The head is preferably truncated to form a flat upper surface within which a tool engaging recess is defined.

The multi-axial assembly further includes a receiver member defining a bore therethrough from a top end to a bottom end. The bore includes a recess for receiving the head of the bone screw, with a lower opening at the bottom end of the receiver member through which the lower portion of the bone screw extends. The receiver member also includes a channel communicating with the recess and having an upper opening at the top end of the receiver member for insertion of the spinal rod.

In a further aspect of the invention, the assembly includes a crown member insertable through the upper opening of the receiver member and slidably disposed within the bore. The crown member has a lower surface contacting the head of the bone screw and an opposite upper surface contacting the spinal rod. In one embodiment, the crown member defines a bore which forms a conical bore at the lower surface contacting the head of the bone screw.

The assembly includes a compression member, such as a set screw, engaged within the bore at the upper opening of the receiver member. The compression member is operable to press the rod against the crown member, which then presses the head of the bone screw into the receiver member recess to thereby fix the head and bone screw at a particular

-7-

angular orientation relative to the spinal rod.

In a further feature of the invention, the head of the bone screw includes a flared edge at the truncated upper surface. The flared edge is configured to penetrate the conical bore of the crown member to form a firm engagement between the two components. The flared edge can also be arranged to penetrate the recess of the receiver member at certain angular orientations of the bone screw head. In another embodiment, the flared edge of the crown member is replaced by a number of circumferential ridges formed around the upper portion of the spherical head of the bone screw. These ridges are preferably configured to engage within the embodiment of the crown member having a spherical recess in its underside. The circumferential ridges include sharpened edges to penetrate into the relatively softer material of the crown member to effect a firm fixation of the bone screw.

In yet another aspect of the invention, the crown member is preferably made of a material that is softer than either the head of the bone screw, or the spinal rod. In one particular embodiment, all the components of the bone screw assembly, including the spinal rod, are formed of titanium. In the case of the crown member, it is preferably formed of a commercially pure titanium, while the remaining components are made of a titanium alloy that is harder than the commercially pure material. When the set screw is tightened with the assembly to clamp the rod, material flow is believed to occur between the set screw and the rod, between the rod and the crown member, and between the crown member and the bone screw. This material flow ensures a solid and lasting fixation.

The present invention provides an assembly that fixes a bone engaging fastener to an elongated member at a plurality of angular orientations relative to the elongated member. The preferred embodiment of a multi-axial bone screw

-8-

assembly provides the advantage of a solid fixation between a spinal rod and a bone screw, regardless of the angle between the two components.

5 A further benefit of the present invention resides in the minimum number of components necessary to effect this solid fixation. Another benefit is realized by the flared edge of the bone screw that enhances the fixation between the components. Other benefits and certain objects of the invention will become apparent upon consideration of the
10 following written description and accompanying figures illustrating one embodiment of the invention.

-9-

DESCRIPTION OF THE FIGURES

FIG. 1 is a side elevational view of a multi-axial bone screw assembly in accordance with one embodiment of the present invention, shown engaged to an elongated spinal rod.

5 FIG. 2 is a cross-sectional view of a multi-axial bone screw assembly as depicted in FIG. 1.

FIG. 3 is a side elevational view of a bone screw for use in the bone screw assembly shown in FIGS. 1 and 2.

10 FIG. 4 is a top elevational view of a receiver member used to support the bone screw of FIG. 3 in the multi-axial bone screw assembly of FIGS. 1 and 2.

FIG. 5 is a side elevational view of the receiver member shown in FIG. 4.

15 FIG. 6 is a top elevational view of a crown member for engagement between the bone screw of FIG. 3 and a spinal rod, in connection with the multi-axial bone screw assembly shown in FIGS. 1 and 2.

FIG. 7 is a side elevational view of the crown member shown in FIG. 6.

20 FIG. 8 is a side elevational partial view of a multi-axial bone screw assembly in accordance with a further embodiment of the present invention, shown engaged to an elongated spinal rod.

25 FIG. 9 is an enlarged side elevational view of the head of a bone screw for use in the bone screw assembly shown in

-10-

FIGS. 1 and 8, but most preferably in the embodiment shown in FIG. 8.

FIG. 10 is an enlarged side elevational view of a crown member for use in a bone screw assembly such as depicted in
5 FIGS. 1 and 8, but most preferably as shown in FIG. 8.

FIG. 11 is a side elevational view of an insertion tool for inserting the crown member shown in FIG. 10 into the multi-axial bone screw assembly such as depicted in FIG. 8.

-11-

DESCRIPTION OF THE PREFERRED EMBODIMENT

For the purposes of promoting an understanding of the principles of the invention, reference will now be made to the embodiments illustrated in the drawings and specific language will be used to describe the same. It will nevertheless be understood that no limitation of the scope of the invention is thereby intended, such alterations and further modifications in the illustrated device, and such further applications of the principles of the invention as illustrated therein being contemplated as would normally occur to one skilled in the art to which the invention relates.

Referring to FIGS. 1 and 2, the general components of a multi-axial bone screw assembly 10 in accordance with the present invention are shown. The multi-axial bone screw assembly 10 includes a bone screw 11 configured to engage a bone, such as a vertebra. The assembly further includes a receiver member 12 for supporting the bone screw, a crown member 13 for engagement with the bone screw, and a compression member 14 that is disposed within the receiver member 12 to clamp a spinal rod R within the assembly 10.

In accordance with one aspect of the invention, the bone screw 11 is configured as shown in FIG. 3. In particular, the bone screw 11 includes a threaded shank 21 that preferably carries threads configured to solidly anchor the bone screw within a bone. Most preferably, the threads are cancellous threads, or threads readily adapted for solid fixation within the cancellous bone of the vertebral body. It is understood that the threaded shank 21 can have a variety of configurations depending upon the nature of the bone within which the bone screw 11 is engaged. Moreover, the length of the threaded shank 21 can be adjusted depending upon the bone within which the screw is driven.

-12-

In one specific embodiment, the threaded shank 21 has a length of about 1.75 inches, and is configured with threads for engagement within the pedicle of a lumbar vertebra.

The bone screw 11 further includes a head 22 at its upper or proximal portion. The head 22 defines a partially spherical outer surface 23. It has been found that a spherical surface is optimum in providing multi-axial angular variations of the position of the bone screw 11 relative to a spinal rod R. In one specific embodiment, the head 22, and specifically the spherical surface 23, resides at a diameter of 0.315 inches. As shown in FIG. 3, the head 22 does not form a complete sphere, having been truncated at an upper surface 24. Again, in a specific embodiment, the head 22 has a height of 0.196 inches as measured between the truncated upper surface 24 and the lower truncation of the head at the transition shank 27.

The head 22 defines a tool receiving recess 25 projecting into the head from the upper surface 24. In one embodiment, the recess 25 is a hex recess to receive a hex end driving tool as is known in the art. It is of course understood that the tool receiving recess 25 can have various configurations, such as a TORX® configuration.

As mentioned above, the head 22 is engaged to the threaded shank 21 of the bone screw 11 by way of a transition shank 27. As shown in FIG. 3 in accordance with the preferred embodiment, the transition shank 27 has a diameter that is less than the diameter of the head 22. As shown in FIG. 2, the reduced diameter transitional shank 27 provides clearance for the bone screw when it is oriented at its greatest angle relative to the receiver member 12. In one specific embodiment, the transition shank 27 has a diameter of 0.236 inches, which is about 0.08 inches smaller than the diameter of the head 22.

Referring again to FIG. 2, a receiver member 12 is provided to support both the bone screw head 22 and the

-13-

spinal rod R. The details of the receiver member 12 can also be seen with reference to FIGS. 4 and 5. In one aspect of the invention, the receiver member 12 includes a U-shaped body 30 defining a first branch 31 and a second branch 32.

5 The branches form a channel 33 between each other. The channel terminates in an edge 33a on opposite sides of the U-shaped body 30. Preferably, the channel 33 has a width that is slightly larger than the diameter of a spinal rod to which the bone screw 11 is to be engaged. The channel 33
10 has an opening 33b at the top of the member 12 for insertion of the rod R, bone screw 11 and crown member 13.

The receiver member 12 further defines a central bore 34 through the body 30. The lowermost portion of the bore 34 defines a tapered recess 35 within which the head 22 of the
15 bone screw 11 resides, as shown in FIG. 2. The central bore also includes a crown member recess 36 that is directly above the tapered recess 35. The crown member recess opens into a threaded portion 37 which extends to the top opening 33b of the channel 33. The receiver member 12 is preferably
20 sized for minimal bulk and minimum prominence above the spine. In one specific embodiment, the receiver member has a height of about 0.597 inches. In this specific embodiment, a rod disposed within channel 33 can sit as low as 0.2 inches above the surface of the vertebra when the
25 receiver member 12 contacts the bone.

In one aspect of the receiver member 12, opposite tool recesses 38 are provided in each of the branches 31 and 32. The tool recesses are configured to be engaged by an insertion tool, such as an insertion tool used to insert
30 spinal hooks into the spine. The receiver member 12 can also define a number of gripping holes 39 at the laterally adjacent sides of the body. In the specific illustrated embodiment, four such holes are provided on both sides of the receiver member 12. These gripping holes can be engaged
35 by an appropriately configured gripping tool to support the

-14-

receiver member 12 during tightening of the bone screw and the other components of the bone screw assembly 10.

In the preferred embodiment, the central bore 34 exits the U-shaped body 30 at a bottom opening 34a. The bottom opening 34a has a diameter that is smaller than the diameter of the head of the bone screw. Consequently, the bone screw is inserted through the upper opening 33b of the channel 33 and through the central bore 34 until it contacts the lower opening 34a of the bore 34. In one specific embodiment, the lower opening 34a has a diameter of 0.297 inches which is about .02 inches smaller than the diameter of the bone screw head 22. The tapered recess 35 then expands from this diameter of the lower bore 34a to a larger diameter adjacent the crown member recess 36. In one specific embodiment, this larger diameter is 0.370 inches, which is larger than the outer diameter of the head 22 of the bone screw 11. In this specific embodiment, the tapered recess 35 is tapered at an angle of about 11° from the lower opening 34a to the crown member recess 36. Again, in the specific embodiment, this tapered recess has a height between the two ends of the recess of about 0.188 inches. The tapered recess 35 can assume various orientations and angles, depending upon the range of angles desired for the bone screw 11 to achieve relative to the spinal rod. As shown in FIG. 2, the bone screw 11 can be oriented at an angle A relative to a plane extending through the center of the spinal rod R. The range of this angle A can be determined by the diameter of the transition shank 27 of the bone screw 11 as well as the angle of the tapered recess 35. In the specific illustrated embodiment, the bone screw is capable of achieving a range of angles A up to 20°.

The threaded portion 37 of the U-shaped body 30 is configured to engage the compression member 14, which is preferably a set screw. In particular, referring to FIG. 2, the set screw 14 includes a threaded plug 55 having threads

-15-

configured to engage the threaded portion 37 of the receiver member 12. The set screw 14 also includes a driving head 56 that defines a tool recess 57. In this specific embodiment, the tool recess can be a hex recess. Alternatively, the driving head 56 itself can have an external configuration to receive a driving tool. In accordance with the preferred embodiment, the set screw 14 is a "break-off type" set screw in which the driving head 56 is severed from the threaded plug 55 at a shear zone 58. As is known in the art, the head of the break-off set screw will sever at a pre-determined torque, the torque being based upon the resistance offered by the head 22 of the bone screw, crown member 13 and the spinal rod R as they are compressed together between the receiver member 12 and the set screw 14.

In a further aspect of the invention, the bone screw assembly 10 includes a crown member 13. The details of the crown member are shown in FIGS. 6 and 7. In particular, the crown member 13 is hollow and defines a conical bore 45 at its lower end. As shown in FIG. 2, the head 22 of the bone screw 11 at least partially resides within the conical bore 45 of the crown member when the screw assembly 10 is affixed together. The crown member 13 further defines a tool insertion bore 46 that can be oriented directly over the tool receiving recess 25 of the bone screw 11 when the bone screw is situated within the receiver member 12. Crown member 13 also defines a conical tool relief 47 at the top of the tool insertion bore 46. This relief is oriented at an angle to permit positioning of a driving tool into the head of the bone screw 11 even when the receiver member 12 is not directly aligned with the bone screw.

In another embodiment, the crown member defines a spherical bore at its lower surface for contacting the spherical head of the bone screw.

In yet another aspect of the invention, the crown member

-16-

can be provided with threads matching the threads at the interior of the receiver member. The threads of the crown member have a truncated crest so that the crown member will fit within a chamber in the receiver member between the rod channel and the lower bone screw opening. In this manner, the crown member can be threaded into the receiver member until it drops into the crown chamber. The crown chamber preferably has an outer diameter smaller than the crest diameter of the threaded bore in the receiver member so that the crown member cannot be unscrewed or removed from the receiver member.

Crown crown member 13 also forms a conical outer surface 48 that is preferably complementary with the tapered recess 35 of the receiver member 12. The crown member 13 also includes a rim 49 at its upper end. In accordance with one aspect of the invention, the rim 49 of the crown member 13 has a diameter that is slightly smaller than the diameter of the crown member recess 36. The diameter of the crown member recess 36, and also the rim 49 of the crown member 13, is slightly larger than the inner diameter of the threaded portion 37 of the receiver member 12. In this manner, the crown member 13 can be retained within the crown member recess 36 when the multi-axial bone screw assembly 10 is only loosely connected. In accordance with the preferred embodiment of the invention, the rim 49 can be threaded through the threaded portion 37 of the receiver member 12 from the upper opening 33b of the channel 33 until it is disposed within the crown member recess 36. The rim 49 can also be provided with a single thread to mate with the internal threads of the threaded portion 37, to facilitate insertion of the crown member 13 into the receiver member 12.

In one specific embodiment, the crown member has an outer diameter of 0.358 inches at the rim 49. This diameter is about 0.012 inches larger than the inner diameter of the threaded portion 37, and is about 0.012 inches smaller than

-17-

the diameter of the crown member recess 36. The conical bore 45 is preferably oriented at an angle of about 45°, so that at its open end the conical bore 45 has a diameter of about 0.324 inches, which is larger than the diameter of the head 22 of the bone screw 11.

When the multi-axial bone screw assembly 10 is to be used, the bone screw 11 is inserted into a receiver member 12 so that the screw extends through the bottom opening 34a of the central bore 34. At this point, the receiver member 12 can be supported at the tool recesses 38 by a gripping tool. The tool recess 38 of the bone screw 11 can be engaged by a driving instrument to thread the bone screw 11 into the vertebral bone. Once the bone screw 11 has been driven into its predetermined depth into the bone, the crown member 13 can be placed within the receiver member 12 and oriented on top of the head 22 of the bone screw 11. The receiver member 12 can then be engaged by way of the gripping holes 39 by a gripping tool to support the receiver member as the various components of the assembly 10 are tightened against each other. The spinal rod R can be pushed into the upper opening 33b of the channel 33 and into the channel 33. Once the spinal rod R is brought to bear against the crown member 13, the crown member should assume its final orientation relative to the head 22 of the bone screw 11. As shown in FIG. 2, in this orientation, the flared edge 26 of the head 22 of the bone screw 11 contacts the conical bore 45 of the crown member 13 somewhere above the bottom of the crown member and adjacent the tool insertion bore 46. At this orientation, the flared edge 26 also contacts the tapered recess 35 of the receiver member 12.

With the spinal rod R in position, the set screw 14 can be threaded into the threaded portion 37 of the receiver member 12. As the set screw 14 is tightened further into the receiver member 12, the tapered recess 35 of the

-18-

receiver member 12 and the set screw 14 are drawn toward each other. As this process continues, the spinal rod R presses against the top of the crown member 13, which then presses against the head 22 of the bone screw 11. As the
5 compression continues, the flared edge 26 of the bone screw 22 penetrates or bites into the conical bore 45 of the crown member 13. The flared edge 26 also preferably penetrates the tapered recess 35 of the receiver member 12. The penetration of the flared edge 26 helps prevent
10 disengagement between the crown member, receiver and bone screw head under severe spinal loads, thereby adding a great degree of security of the fixation of the bone screw 11 to the spinal rod R.

As the set screw 13 is tightened further into the
15 threaded portion 37 of the receiver member, the bone screw head 22 resists further movement into the tapered recess 35. Further tightening of the set screw requires greater torque until the screw head 56 is severed from the threaded plug 55 at the shear zone 58. Preferably, the shear zone is
20 disposed within the receiver member 12 so that no portion of the set screw 14 projects beyond the opening 33b of the receiver member.

The present invention contemplates a further embodiment as depicted in FIGS. 8-11. In this embodiment, a
25 multi-axial bone screw assembly 110 includes a bone screw 111, a receiver member 112, a crown member 113 and a set screw 114. In many respects, each of the components of the bone screw assembly 110 are similar to the like components of bone screw assembly 10 shown in FIGS. 1 and 2.

30 The bone screw 111 includes a threaded shank 121 that carries threads for engaging bone, such as a vertebra. The head 122 of the bone screw 111 includes a partially spherical surface 123 that is truncated to define an upper surface 124. A tool receiving recess 125 is formed from the
35 upper surface 124 into the head of the bone screw and is

-19-

configured for engaging a standard driving tool. In this respect, the bone screw 111 is similar in design to the bone screw 11. With this embodiment, however, the partially spherical surface 123 forms more of a complete sphere than
5 does the head 22 of the bone screw 11. Described in another way, the upper surface 124 of the bone screw 111 covers a smaller area than the upper surface 24 of bone screw 11 depicted in FIGS. 2 and 3.

In a further aspect of this embodiment of the bone
10 screw, the head 122 includes a number of circumferential ridges 126 formed around the partially spherical surface 123 and adjacent to the upper surface 124. In the illustrated embodiment, four such ridges 126 are provided, as depicted in FIGS. 8 and 9. As shown most clearly in FIG. 8, the
15 ridges are generally triangular in shape to define a sharp edge. In this respect, each of the ridges are similar to the flared edge 26 of the bone screw 11 of the prior embodiment shown in FIG. 3. While one such circumferential ridge 126 can be provided, the bone screw 11 preferably
20 includes two or more such ridges. In the most preferred illustrated embodiment, four circumferential ridges 126 are formed on the head of the bone screw 111. The ridges are preferably concentrically arranged around the circumference of the partially spherical surface 123 in a pattern so that
25 all of the ridges 126 engage the crown member 113 regardless of the angle of the bone screw 11 relative to the receiver member 110. In other words, as shown in FIG. 8, when the bone screw 111 is rotated to its maximum angle, such as angle A depicted in FIG. 2, all four of the circumferential
30 ridges 126 contact and engage with the crown member 113.

Referring back to FIG. 8, the details of the receiver member 112 will be described. In particular, the receiver member 112 includes a U-shaped body 130 which is similar in construction to the U-shaped body 30 shown in FIGS. 1, 2 and
35 5. The body 130 defines a rod channel 133 within which a

-20-

spinal rod R is received. The U-shaped body 130 also defines a bore 134 extending entirely through the body and intersecting the rod channel 133. The bore opens into a screw opening 135 at the bottom of the U-shaped body 130.

5 The screw opening 135 is sized to accept the threaded shank 121 of the bone screw 111 therethrough in a top-loading fashion. The screw opening 135 has a diameter that is smaller than the largest diameter of the partially spherical head 122 of the bone screw 111. Preferably, the screw

10 opening 135 is flared outward toward the bottom of the U-shaped body 130 to permit angulation of the bone screw 11 relative to the receiver member 112. In one specific embodiment, the screw opening 35 flares outward at an angle of about 25°, thereby leaving ample room for angulation of

15 the bone screw 111 up to the preferred 20° inclination described earlier.

The U-shaped body 130, and more particularly the bore 134, defines a crown chamber 136 adjacent the screw opening 135 at the bottom of the body 130. The crown chamber 136 is

20 preferably cylindrical and is sized to provide ample space around the head of the bone screw 111. Moreover, the crown chamber 136 is sized to receive the crown member 113 therein. Also preferably, the crown chamber 136 has a height that exceeds the height of the portion of the head

25 122 of the bone screw 111 when it is disposed within the screw opening 135. Again, the height of the crown chamber 136 provides space for both the head of the bone screw and the crown member 113.

The bore 134 of the U-shaped body 130 also defines a

30 threaded portion 137 communicating between the top of the body 130 and the crown chamber 136. The threaded portion 137 has a crest diameter, or a maximum inner diameter, that is greater than the maximum inner diameter of the crown chamber 136. The threads of the threaded portion 137 are

35 configured to engage similar threads on the set screw 114.

-21-

In this respect, the U-shaped body 130 is similar to the body 30 of the previous embodiment depicted in FIGS. 1-5.

The details of the crown member 113 can be discerned from FIG. 10. As previously discussed, the crown member 113
5 has an outer diameter that is sized to slide freely within the crown chamber 136 of the U-shaped body 130. In the present embodiment, the crown member 113 defines a spherical recess 142 at its underside. The spherical recess 142 is sized to accept the head 122 of the bone screw 111 in a
10 close tolerance relationship. More particularly, the spherical recess 142 is formed at a radius corresponding to the effective outer radius of the circumferential ridges 126 defined on the head of the bone screw 111. In this manner, as the bone screw assembly 110 is tightened down, the
15 circumferential ridges 126 will bite into and engage the spherical recess 142 of the crown member 113.

In a further aspect of the crown member 113, the member includes outer threads 140. In the specific embodiments, these threads have the same pitch and dimension as the
20 threads of the threaded portion 137 of the U-shaped body 130. Thus, the crown member 113 can be inserted into the crown chamber 136 by threading the crown member through the threaded portion 137 of the body 130. Preferably, the threads 140 include flattened crests 141 so that the crown
25 member 113 has an outer diameter that is smaller than the outer diameter of the threaded portion 137. More specifically, the flattened crests 141 of the crown member 113 have an outer diameter that is slightly less than the diameter of the crown chamber 136. The crown member 113 is
30 preferably slidable within the crown chamber 136. Most preferably, the crown member 113 is sized so that it is fully disposed within the crown chamber 136 and so that no portion of its threads 140 engage any of the threaded
portion 134 of the U-shaped body 130. As a result, with the
35 flattened crests and the placement of the crown member 113

-22-

within the crown chamber 136, there is no substantial likelihood that the crown member will slip out of the receiver member 112 prior to final clamping of the bone screw assembly 110.

5 The crown member 113 includes an annular rim 145 projecting from the top end of the crown member, or more particularly opposite the large opening of the spherical recess 142. This annular rim 145 is intended to be engaged by the spinal rod R when the bone screw assembly 110 is
10 tightened. The annular rim 145 defines a tool bore 147 therethrough that preferably communicates with the spherical recess 142. This tool bore 147 receives a tool provided for inserting the crown member 113 into the receiver member 112.

 Preferably, tool bore 147 and the corresponding tool
15 have a mating configuration that permits easy rotation of the crown member as it is threaded along the threaded portion 134 of the U-shaped body 130. In one embodiment, the insertion tool 150 appears as a shown in FIG. 11. In this embodiment, the tool 150 includes an elongated shank
20 151 forming a tapered tip 152. A handle 153 is provided at the end opposite the tip 152, with the handle being preferably knurled to provide adequate grasping surface. The tapered tip 152 is sized to slide into the tool bore 147 of the crown member 113. In the preferred embodiment, the
25 tapered tip 152 frictionally engages the tool bore 147 of the crown member 113. This frictional engagement is sufficient to allow threading of the crown member 113 into the threaded portion 134 of the receiver member, particularly since the crown member 113 is not being
30 threaded against any component of the assembly or meeting any resistance.

 In one specific embodiment, at least the tapered tip 152 of the tool 150 includes a silicone coating to enhance the frictional grip within the tool bore 147 of the crown member
35 113. Other configurations for the tool 150 and

-23-

particularly the silicone coated tip 152, are contemplated, provided that the tool 150 can readily engage the crown member and disengage the crown member leaving it within the chamber 136.

5 The next component of the bone screw assembly 110 is the set screw 114, the details of which are shown most clearly in FIG. 8. This set screw 114 is similar to the set screw 14 of the previous embodiment in that it includes a threaded plug 155, a driving head 156, a tool recess 157 and a shear
10 zone 158. The set screw 114 also includes a rod engagement surface 159 projecting from the bottom surface of the component. Where this embodiment of the set screw 114 deviates from the design of the prior embodiment is in the provision of a removal tool recess 160 within the threaded
15 plug 155 of the set screw. Once the driving head 156 has been sheared off at the shear zone 158, the removal tool recess 60 allows the threaded plug 155 to be removed by an appropriate tool. This need may arise in the case of a
20 revision surgery where it is necessary to reposition the spinal construct or to remove the bone screw assembly 110 from the vertebra of a patient.

 The multi-axial bone screw assembly 110 is implanted within the patient in substantially the same manner as the assembly 10 in the embodiment of FIGS. 1 and 2. In one
25 aspect of this preferred embodiment, the crown member 113 is formed of a material that is softer than either the rod R or the bone screw 111. In one specific embodiment, all of the components of the bone screw assembly 110 are formed of a titanium material. The crown member 113 in this specific
30 embodiment is formed of a commercially pure titanium while the remaining components are formed of a titanium alloy. In this way, the crown member 113 is softer than the other components. Consequently, when the entire assembly is tightened down, namely by threading the set screw 114 within
35 the threaded portion 137 of the receiver member 112, the

-24-

crown member 113 endures some material flow as the rod R embeds within the annular rim 145 of the crown member 113, and as the head 122 of the bone screw 111, and particularly the circumferential ridges 126, embed within the spherical
5 recess 142. This material flow increases the degree of fixation of all of the components. In another specific embodiment, the set screw 114 can also be formed of a commercially pure titanium so that it too will endure some material flow at the rod engagement surface 159 of the
10 threaded plug 155. These same differential material properties can be implemented in the bone screw assembly 10 of the embodiment of FIGS. 1-7.

While the invention has been illustrated and described in detail in the drawings and foregoing description, the
15 same is to be considered as illustrative and not restrictive in character, it being understood that only the preferred embodiment has been shown and described and that all changes and modifications that come within the spirit of the invention are desired to be protected.

20 For example, the specific embodiments of the multi-axial bone screw assemblies 10, 110 can be sized for placement at any level of the spine. Of course, it is understood that the relative size of the components of the assemblies will be modified for the particular vertebra to be instrumented.
25 Likewise, the relative dimensions of the bone screws and receiver members can be modified to permit greater or lesser degrees of angulation of the bone screw relative to the spinal rod.

In the preferred embodiment, the components of the
30 assemblies 10, 110 are formed of stainless steel. It is contemplated that the assemblies 10, 110 can be formed of other biocompatible materials, such as titanium, and even materials that permit bone ingrowth.

Further, while the preferred embodiments of the
35 invention concern a bone screw, other bone fixation members

-26-

What is claimed is:

1. A spinal fixation assembly, comprising:
 - an elongated member configured for placement adjacent and along the length of the spine;
 - 5 a bone engaging fastener, said fastener having a lower portion configured for engaging a vertebra and a head, said head being at least partially spherical in configuration;
 - a receiver member defining a bore therethrough from a top end to a bottom end, said bore including a recess for
10 receiving said head of said bone engaging fastener therein, said recess having a lower opening at said bottom end of said receiver member through which said lower portion of said fastener extends, said member also including a channel communicating with said recess and having an upper opening
15 at said top end of said receiver member, said channel being configured to receive said elongated member therein adjacent said recess;
 - a crown member insertable through said upper opening and slidably disposed within said bore, said crown member having
20 a lower surface contacting said head of said fastener and an opposite upper surface contacting said elongated member; and
 - a compression member engaged within said bore at said upper opening, said compression member operable to press said elongated member against said crown member, to thereby
25 fix said fastener head between said crown member and said recess of said receiver member.
2. The spinal fixation assembly according to claim 1, wherein:
 - said bore includes an internally threaded portion
30 adjacent said upper opening; and
 - said compression member is a set screw having threads for engagement with said internally threaded portion.

-25-

can be adapted to implement the multi-axial capabilities of this invention. For instance, a vertebral hook can be equipped with a spherical head to be clamped to a spinal rod by way of the components of assembly 10.

5 It is also understood that while the preferred embodiments of the invention engage a bone screw to a rod, various longitudinal members are contemplated. For example, an elongated bar can be disposed within the channel of the receiver member to be clamped between the crown member and
10 set screw. The present invention can be applied equally well to smooth rods or bars, or longitudinal members having various surface features, such as knurling or threading.

-27-

3. The spinal fixation assembly according to claim 1, wherein said head of said bone engaging fastener includes a truncated upper surface, and defines a tool receiving recess through said upper surface.

5 4. The spinal fixation assembly according to claim 1, wherein said head of said bone engaging fastener includes a truncated upper surface and a flared edge adjacent said upper surface, said flared edge having a diameter greater than the diameter of spherical diameter of said fastener
10 head, and said flared edge arranged to penetrate at least said lower surface of said crown member when said fastener head is fixed between said crown member and said recess.

5. The spinal fixation assembly according to claim 1, wherein said lower surface of said crown member is a conical
15 surface.

6. The spinal fixation assembly according to claim 1, wherein said crown member defines a bore therethrough, said bore including said lower surface contacting said head of said fastener, and said bore including a tool insertion bore
20 configured to receive a driving tool to engage said head of said fastener through said bore of said crown member.

7. The spinal fixation assembly according to claim 1, wherein:

said bore of said receiver member includes a portion for
25 engaging said compression member and a crown member bore between said portion and said recess, said portion having an inner diameter smaller than an inner diameter of said crown member bore; and

said crown member bore includes an upper rim having a
30 diameter smaller than the inner diameter of said crown

-28-

member bore but larger than the inner diameter of said portion of said bore.

8. The spinal fixation assembly according to claim 1, wherein said recess is tapered from a larger diameter to a smaller diameter at said bottom end.

9. The spinal fixation assembly according to claim 8, wherein said crown member includes a conical outer surface configured for complementary engagement with said tapered recess of said receiver member.

10. The spinal fixation assembly according to claim 1, wherein:

said bore includes an internally threaded portion adjacent said upper opening and a crown chamber defined between said threaded portion and said lower opening, said crown chamber sized to slidably receive said crown member therein; and

said crown member includes external threads sized to threadedly engage said internally threaded portion of said bore of said receiver member so that said crown member can be threaded through said threaded portion and into said crown chamber.

11. The spinal fixation assembly according to claim 10, wherein said external threads of said crown member are truncated so that the crest diameter of said external threads is less than the crest diameter of said threaded portion of said bore of said receiver member.

12. The spinal fixation assembly according to claim 1, wherein said crown member includes an insertion tool bore opposite said lower surface, said tool bore defining a

-29-

diameter and configured to receive a cylindrical portion of an insertion tool in press fit engagement.

13. The spinal fixation assembly according to claim 1, wherein said head of said bone engaging fastener includes:

- 5 a truncated upper surface;
 a substantially spherical surface between said upper surface and said lower portion; and
 at least one circumferential ridge defined on said spherical surface adjacent said truncated upper surface,
10 said at least one ridge configured to penetrate a portion of said lower surface of said crown member.

14. The spinal fixation assembly according to claim 13, wherein said lower surface of said crown member is a spherical surface.

- 15 15. The spinal fixation assembly according to claim 14, wherein:

 said spherical lower surface of said crown member is sized to fit over an upper portion of said head of said bone engaging fastener adjacent said truncated upper surface; and

- 20 said head of said bone engaging fastener includes a plurality of said circumferential ridges concentrically defined on said spherical surface and arranged on said bone engaging fastener head so that all of said plurality of ridges engage said spherical lower surface of said crown
25 member when said bone engaging fastener is oriented at a predetermined angle relative to said crown member.

16. The spinal fixation assembly according to claim 13, wherein said head of said bone engaging fastener includes four annular ridges.

- 30 17. The spinal fixation assembly according to claim 1,

-30-

wherein said crown member is formed of a softer material than the material of said elongated member.

18. The spinal fixation assembly according to claim 1,
wherein said crown member is formed of a softer material
5 than the material of said elongated member and said head of
said bone engaging fastener.

SMC00/2112

J. 1 821. 8

SMC00/2112